

CERTIFICATE UNDER 37 CFR § 1.10 OF MAILING BY "EXPRESS MAIL"

EV 847360140 US

April 24, 2006

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I hereby certify that this correspondence is being deposited with the United States Postal Services "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By:

Sarah M. Barnett



PATENT

Customer No. 22,852

Attorney Docket No. 07579-0006-01000

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
)  
Graham Edmund KELLY ) Group Art Unit: 1616  
)  
Application No.: 09/986,509 ) Examiner: Edward J. Webman  
)  
Filed: November 9, 2001 ) Confirmation No. 5532  
)  
For: **TREATMENT OR PREVENTION** )  
**OF MENOPAUSAL SYMPTOMS** )

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**UNDER 37 C.F.R. § 1.97(c)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents listed on the enclosed IDS Form PTO/SB/08. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final action, Quayle action, or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

04/27/2006 BABRAHA1 00000072 060916 09986509

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Copies of the listed foreign and non-patent literature documents are enclosed. Copies of the U.S. patents and patent publications are not enclosed.

The United States Court of Appeals for the Federal Circuit held in *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 66 U.S.P.Q.2d 1801 (Fed. Cir. 2003), that an “adverse decision” by another examiner may meet the materiality standard under the amended Rule 56, and thus, Applicant should disclose prior rejections of “substantially similar claim[s]” to the Office. Accordingly, although Applicant is not representing that the Office Actions in the co-pending applications are material to the present application and are not admitting that any of the other claims are substantially similar, out of an abundance of caution, Applicant has listed the substantive Office Actions filed in co-pending applications on the enclosed PTO/SB/08 and has enclosed copies of those documents, as well.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the enclosed form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute “prior art.” If the Examiner applies any of the documents as prior art against any claims in the application and Applicant determines that the cited documents do not constitute “prior art” under United States law, Applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the claimed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: April 24, 2006

By: Elisabeth Barek  
Elisabeth Jaffe Barek  
Reg. No. 46,797

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IDS Form PTO/SB/08: Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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**Complete if Known**

Application No.	09/986,509
Filing Date	November 9, 2001
First Named Inventor	Graham E. KELLY
Art Unit	1616
Examiner Name	Edward J. WEBMAN
Attorney Docket Number	07579.0006-01000

**U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS**

Examiner Initials	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
		US 6,261,565	07-17-2001	Empie et al.	
		US 2005/0131047	06-16-2005	Kelly et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
		Country Code Number Kind Code (if known)				
		EP 0 682 877 B1	04-02-2003	Nichimo Co. Ltd.		
		JP 01-258669	10-16-1989	Kikkoman Corp.		Abstract
		WO 97/46208 A2	12-11-1997	Mt. Sinai School of Medicine of the City of New York		
		WO 98/04248 A1	02-05-1998	Energetics, Inc.		
		WO 98/21946 A1	05-28-1998	Internutria, Inc.		
		WO 98/25588 A1	06-18-1998	Gorbach		
		WO 99/45923 A1	09-16-1999	Merck & Co., Inc.		
		WO 99/48496 A1	09-30-1999	Novogen Research Pty. Ltd.		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
		"Novogen launches Rimostil," Press Release, 2 pages, <a href="http://www.novogen.com/news/newsPopup.cfm?id=22">http://www.novogen.com/news/newsPopup.cfm?id=22</a> (June 22, 2000).	
		BERKOW, R. (Ed.) et al., <u>The Merck Manual of Diagnosis and Therapy</u> , 16 <sup>th</sup> Ed., Merck Research Laboratories, Rahway, N.J., pp. 1357-1359, 1793-1795 (1992).	
		BUDAVARI, S. (Ed.) et al., <u>The Merck Index</u> , 11 <sup>th</sup> Ed., Merck & Co., Inc., Rahway, N.J., p. 663, Monograph No. 4157 (1989).	
		KNIGHT, D.C. et al., "Phytoestrogens - A short review," <i>Maturitas</i> 22(3):167-175 (1995).	
		MARKOVITS, J. et al., "Inhibitory Effects of the Tyrosine Kinase Inhibitor Genistein on Mammalian DNA Topoisomerase II," <i>Cancer Res.</i> 49:5111-5117 (1989).	
		NAIM, M. et al., "Antioxidative and Antihemolytic Activities of Soybean Isoflavones," <i>J. Agric. Food Chem.</i> 24(6): 1174-1177 (1976).	
		PRADHAN, S.N. (Ed.), <u>Pharmacology in Medicine: Principles and Practice</u> , SP Press Intl., Inc., Maryland, pp. 466-467 (1986).	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<i>Application No.</i>	09/986,509	
			<i>Filing Date</i>	November 9, 2001	
			<i>First Named Inventor</i>	Graham E. KELLY	
			<i>Art Unit</i>	1616	
			<i>Examiner Name</i>	Edward J. WEBMAN	
Sheet	2	of	3	<i>Attorney Docket Number</i>	07579.0006-01000

NON PATENT LITERATURE DOCUMENTS			
		REYNOLDS, J. (Ed.), <u>Martindale: The Extra Pharmacopoeia</u> , 13th Ed., The Pharmaceutical Press, London, UK, pp. 856, 1060, 1169, and 1170 (1993).	
		WANG, H.J. et al., "Isoflavone Content in Commercial Soybean Foods," <i>J. Agric. Food Chem.</i> 42:1666-1673 (1994)	
		WINTROBE, M.M. (Ed.), <u>Harrison's Principles of Internal Medicine</u> , 7th Ed., McGraw Hill, Tokyo, Japan, pp. 1968-1969 (1974).	
		International Search Report for PCT/AU98/00313, mailed on June 30, 1998, 3 pages.	
		International Preliminary Examination Report for PCT/AU98/00313, dated April 14, 1999, 5 pages.	
		EPO Supplementary Search Report for EP Appl. No. 98916669.9, dated May 26, 2003, 3 pages.	
		EPO Examination Report for EP Appl. No. 98916669.9, dated October 27, 2003, 3 pages.	
		Office Action issued in U.S. Application No. 09/077,590 on July 9, 1999 (Attorney Docket No. 07579.0006-00000).	
		Office Action issued in U.S. Application No. 09/077,590 on April 27, 2000 (Attorney Docket No. 07579.0006-00000).	
		Amendment and Response filed in U.S. Application No. 09/077,590 on October 27, 2000 (Attorney Docket No. 07579.0006-00000).	
		Office Action issued in U.S. Application No. 09/077,590 on February 9, 2001 (Attorney Docket No. 07579.0006-00000).	
		Amendment filed in U.S. Application No. 09/077,590 on May 31, 2001 (Attorney Docket No. 07579.0006-00000).	
		Office Action issued in U.S. Application No. 09/647,092 on October 23, 2001 (Attorney Docket No. 07579-0013-00000).	
		Amendment filed in U.S. Application No. 09/647,092 on March 25, 2002 (Attorney Docket No. 07579-0013-00000).	
		Office Action issued in U.S. Application No. 09/647,092 on June 18, 2002 (Attorney Docket No. 07579-0013-00000).	
		Amendment and Response After Final filed in U.S. Application No. 09/647,092 on December 17, 2002 (Attorney Docket No. 07579-0013-00000).	
		Notice of Allowance and Notice of Allowability with Statement of Reasons issued in U.S. Application No. 09/647,092 on April 8, 2003 (Attorney Docket No. 07579-0013-00000).	
		Office Action mailed in U.S. Patent Application No. 10/459,537 on December 20, 2005 (Attorney Docket No. 07579-0013-01000).	
		Office Action issued in U.S. Patent Application No. 09/914,035 on December 18, 2002 (Attorney Docket No. 07579-0015-00000).	
		Office Action issued in U.S. Patent Application No. 10/600,004 on June 17, 2004 (Attorney Docket No. 07579-0015-01000).	
		Amendment and Response filed in U.S. Patent Application No. 10/600,004 on December 13, 2004 (Attorney Docket No. 07579-0015-01000).	
		Final Office Action issued in U.S. Patent Application No. 10/600,004 on April 13, 2005 (Attorney Docket No. 07579-0015-01000).	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT***(Use as many sheets as necessary)*

Sheet

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<i>Filing Date</i>	November 9, 2001
<i>First Named Inventor</i>	Graham E. KELLY
<i>Art Unit</i>	1616
<i>Examiner Name</i>	Edward J. WEBMAN
<i>Attorney Docket Number</i>	07579.0006-01000

**NON PATENT LITERATURE DOCUMENTS**

	Amendment after Final filed in U.S. Patent Application No. 10/600,004 on October 12, 2005 (Attorney Docket No. 07579-0015-01000).	
	Advisory Action issued in U.S. Patent Application No. 10/600,004 on November 16, 2005 (Attorney Docket No. 07579-0015-01000).	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.